

DERMABOND ADVANCED (in CE Mark Codes DNX6 and DNX12) include bleeding, skin edge necrosis, seroma, and hematoma.

**DIRECTIONS FOR USE**

1. The application of DERMABOND ADVANCED™ Adhesive requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of DERMABOND ADVANCED™ Adhesive (i.e., anesthetize, irrigate, debride, ensure hemostasis, and close deep layers making sure that the wound edges can be easily approximated).
2. Pat the wound dry with dry, sterile gauze to ensure direct contact of the DERMABOND ADVANCED™ Adhesive to the skin. Moisture accelerates DERMABOND ADVANCED™ Adhesive's polymerization and may affect wound closure results.
3. To prevent inadvertent flow of liquid DERMABOND ADVANCED™ Adhesive to unintended areas of the body, the wound should be maintained in a horizontal position and the DERMABOND ADVANCED™ Adhesive should be applied from above the wound.
4. DERMABOND ADVANCED™ Adhesive should be used immediately after crushing the ampoule, since the liquid DERMABOND ADVANCED™ Adhesive will flow freely from the tip for only a few minutes.
5. Refer to the instructions on the package for crushing the ampoule and expressing the liquid adhesive. Remove the applicator from the blister package. Hold the applicator with the thumb and a finger away from the patient to prevent any unintentional placement of the liquid DERMABOND ADVANCED™ Adhesive into the wound or on the patient. With the applicator tip pointing downward, apply pressure at the midpoint of the bulb to crush the ampoule. Gently squeeze the applicator sufficiently to moisten the internal filter with the liquid adhesive. Stop squeezing and allow the liquid DERMABOND ADVANCED™ Adhesive to draw back into the applicator.

6. Approximate the wound edges with gloved fingers or sterile forceps. Slowly apply the liquid DERMABOND ADVANCED™ Adhesive in one continuous layer to the surface of the approximated wound edges using a gentle brushing motion. Maintain manual approximation of the wound edges for approximately 60 seconds after the application. The width of the layer can be increased or decreased by adjusting the amount of pressure applied to the bulb during application.

NOTE: DERMABOND ADVANCED™ Adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. DERMABOND ADVANCED™ Adhesive is to be applied in one continuous layer onto a dry wound will minimize the sensation of heat. Applying a second layer is not required or recommended. If a second layer of DERMABOND ADVANCED™ Adhesive is applied or if large droplets of liquid are not spread thinly, the patient may experience an increased sensation of heat or discomfort. Avoid excessive pressure of the applicator tip against the wound edges or surrounding skin to avoid forcing the wound edges apart and allowing DERMABOND ADVANCED™ Adhesive into the wound. Full apposition strength is expected to be achieved within minutes after the adhesive is applied. Full polymerization is expected when the DERMABOND ADVANCED™ Adhesive layer is no longer sticky.

7. Do not apply liquid or ointment medications onto wounds closed with DERMABOND ADVANCED™ Adhesive because these substances can weaken the polymerized film, leading to dehiscence (skin edge separation).
8. Protective dry dressings such as gauze may be applied only after DERMABOND ADVANCED™ Adhesive film is completely polymerized: not tacky to the touch after a few minutes. Allow the DERMABOND ADVANCED™ Adhesive to fully polymerize before applying a bandage.

9. Patients should be instructed to not pick at the polymerized film of DERMABOND ADVANCED™ Adhesive. Picking at the film can disrupt its adhesion to the skin and cause dehiscence (skin edge separation).
10. Patients should be instructed that until the polymerized film of DERMABOND ADVANCED™ Adhesive has sloughed naturally (usually in 5–10 days), there should be only transient wetting of the treatment site. Patients may immediately shower or bathe the site gently as directed by their physician. The site should not be scrubbed, soaked, or exposed to prolonged wetness until after the film has sloughed naturally and the physician has determined that the wound is adequately healed. Patients should be instructed not to swim during this period.
11. If removal of DERMABOND ADVANCED™ Adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the DERMABOND ADVANCED™ Adhesive film to help loosen the bond. Peel off the film; do not pull the skin edges apart.

**HOW SUPPLIED**

DERMABOND ADVANCED™ Adhesive is supplied sterile, in a pre-filled, single-use applicator. The pen style applicator consists of a crushable ampoule contained within a plastic applicator. The applicator contains the liquid adhesive. The applicator is supplied in a blister package to maintain the sterility of the device until opened or damaged.

DERMABOND ADVANCED™ Adhesive is available in boxes of 6 or 12 applicators.

**STORAGE**

Recommended storage conditions: below 30°C, 86°F, away from moisture, direct heat, and direct light. Do not use after expiry date.

**STERILITY**

DERMABOND ADVANCED™ Adhesive has been sterilized by dry heat and ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard any unused material following completion of each medical procedure.

**STERILE SINGLE USE ONLY**

30°C 86°F max Upper Limit of Temperature	Keep away from sunlight	<b>Rx only</b> CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Contents: Vial
Use By	<b>STERILE</b> ↓ Sterilized using steam or dry heat	Caution	Crush Vial After Opening the Package
Manufacturer	<b>STERILE</b>   EO Sterilized using ethylene oxide	Do not reuse	<b>REF</b> Reorder number
<b>LOT</b> Batch number	Do not use if package is damaged or open	Do not resterilize	

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PM72434E



**TOPICAL SKIN ADHESIVE**  
(2-Octyl Cyanoacrylate)

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## TOPICAL SKIN ADHESIVE

(2-Octyl Cyanoacrylate)

### DESCRIPTION

DERMABOND ADVANCED™ Topical Skin Adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet No. 2. It is provided as a single-use applicator in a blister package. The pen style applicator is composed of a crushable ampoule contained within a plastic applicator. As it is applied to the skin, the liquid is syrup-like in viscosity and polymerizes within minutes. Studies have shown that following application, DERMABOND ADVANCED™ Adhesive acts as a barrier to prevent microbial penetration as long as the adhesive remains. See DIRECTIONS FOR USE.

### INDICATIONS

DERMABOND ADVANCED™ Adhesive is intended for topical application only, to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. DERMABOND ADVANCED™ Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

### CONTRAINDICATIONS

- Do not use on any wound with evidence of active infection, gangrene, or wounds of decubitus etiology.

- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin which may be regularly exposed to body fluids or with dense natural hair (e.g. scalp).
- Do not use on patients with a known hypersensitivity to cyanoacrylate, formaldehyde, or benzalkonium chloride.

### WARNINGS

- DERMABOND ADVANCED™ Adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as surgical gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of DERMABOND ADVANCED™ Adhesive may be accelerated by water or fluids containing alcohol. DERMABOND ADVANCED™ Adhesive should not be applied to wet wounds.
- DERMABOND ADVANCED™ Adhesive should not be applied to the eye. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- When closing facial wounds near the eye with DERMABOND ADVANCED™ Adhesive, position the patient so that any runoff of adhesive is away from the eye. The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective in preventing inadvertent flow of adhesive into the eye. DERMABOND ADVANCED™ Adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where DERMABOND ADVANCED™ Adhesive is intended to adhere. Use of DERMABOND ADVANCED™ Adhesive near the eye has inadvertently caused some patients' eyelids to be sealed shut. In some of these

cases, general anesthesia and surgical removal has been required to open the eyelid.

- DERMABOND ADVANCED™ Adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction. Avoid excessive pressure of the applicator tip against wound edges or surrounding skin. This can force the wound edges apart and allow adhesive into the wound. DERMABOND ADVANCED™ Adhesive should be applied with a light brushing motion of the applicator tip over easily approximated wound edges.
- DERMABOND ADVANCED™ Adhesive should not be used in areas of high skin tension or across areas in which tension may increase, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period or unless skin tension has been removed by application of another wound closure device (e.g., sutures or skin staples) prior to application of DERMABOND ADVANCED™ Adhesive.
- As with all wounds, DERMABOND ADVANCED™ Adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain, and purulent exudate, should be evaluated and treated according to standard practice for infection.
- DERMABOND ADVANCED™ Adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- DERMABOND ADVANCED™ Adhesive should only be used after wounds have been thoroughly and adequately cleaned and debrided in accordance with standard surgical practice.
- DERMABOND ADVANCED™ Adhesive polymerizes through an exothermic reaction in which a small amount of heat is released.

DERMABOND ADVANCED™ Adhesive is to be applied in one continuous layer.

NOTE: Applying DERMABOND ADVANCED™ Adhesive in one continuous layer onto a dry wound will minimize the sensation of heat. Applying a second layer is not required or recommended. If a second layer of DERMABOND ADVANCED™ Adhesive is applied or if large droplets of liquid are not spread thinly, the patient may experience an increased sensation of heat or discomfort.

NOTE: Excessive pressure of the applicator tip against the wound edges or surrounding skin can result in forcing the wound edges apart and allowing DERMABOND ADVANCED™ Adhesive into the wound. DERMABOND ADVANCED™ Adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome.

- DERMABOND ADVANCED™ Adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize DERMABOND ADVANCED™ Adhesive.
- Do not place DERMABOND ADVANCED™ Adhesive in a procedure pack/tray that will be sterilized prior to use. Exposure of DERMABOND ADVANCED™ Adhesive, to excessive heat (as in autoclaves or ethylene oxide sterilization) or radiation (such as gamma or electron beam) will increase its viscosity and may render the product unusable.

### PRECAUTIONS

- Do not apply liquid or ointment medications or other substances to the wound after closure with DERMABOND ADVANCED™ Adhesive, as these substances can weaken the polymerized film and allow for dehiscence (skin edge separation). Prior to application, cleanse the application site thoroughly to remove any remaining blood, fluids or topical medications/anesthetics.
- DERMABOND ADVANCED™ Adhesive, as a liquid, is syrup-like in viscosity. To prevent inadvertent flow of liquid DERMABOND ADVANCED™

Adhesive to unintended areas, the wound should be maintained in a horizontal position, with DERMABOND ADVANCED™ Adhesive applied from above.

- Hold applicator away from yourself and the patient with the tip pointing down and break the ampoule close to the center of the bulb one time only. Do not crush the contents of the applicator repeatedly as further manipulation of the applicator may cause glass shard penetration of the outer tube. Glass shard penetration can result in inadvertent skin punctures, which may result in the transmission of bloodborne pathogens.
- DERMABOND ADVANCED™ Adhesive should be used immediately after crushing the ampoule because the adhesive will polymerize in the applicator, rendering the device unusable.
- If unintended bonding of intact skin occurs, peel the adhesive from the skin, but do not pull the skin edges apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, or soap are not expected to immediately loosen the bond.

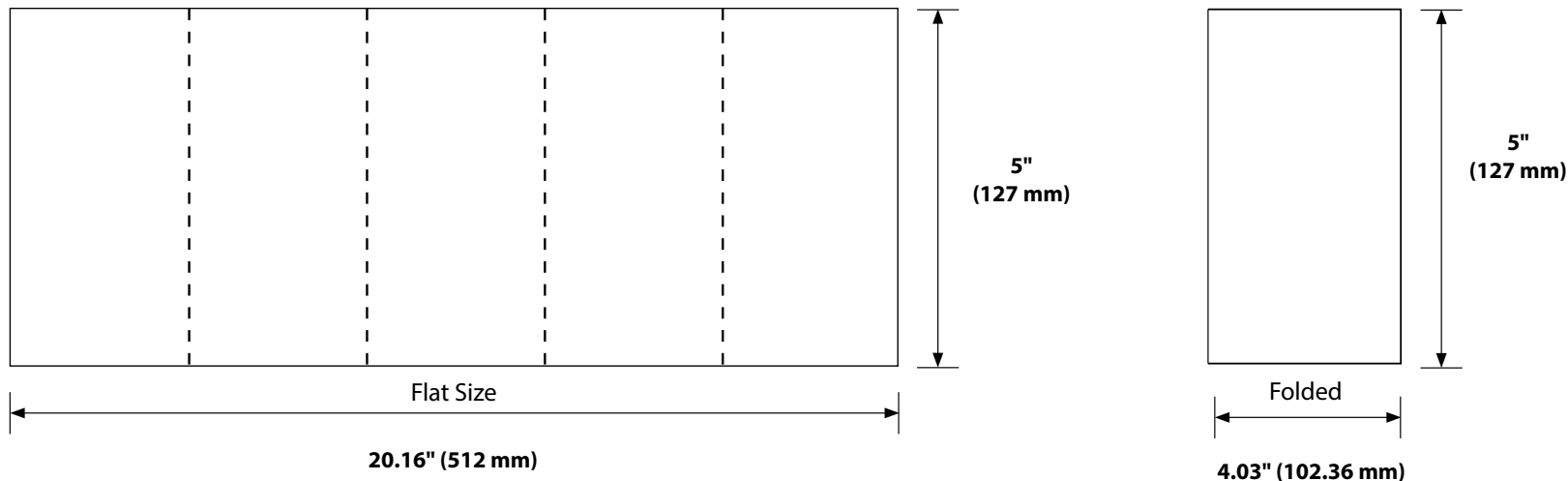
### ADVERSE REACTIONS

Adverse reactions related to either the wound closure procedure or the use of DERMABOND ADVANCED™ Adhesive are possible. The following events have been identified as potentially associated with the wounds closed with DERMABOND ADVANCED™ Adhesive.

- Infection (redness more than 3-5 mm from the wound margin, swelling, purulent discharge, pain, increased skin temperature, fever)
- Acute inflammation (erythema, edema, pain, warmth)
- Dehiscence (Skin Edge Separation)
- Excessive itching
- Skin blistering

### IFU PRINTING SPECIFICATION SHEET

#### PAGE LAYOUT



TITLE <b>DERMABOND ADVANCED™</b>		DESCRIPTION <b>Domestic IFU</b>		LAB NUMBER <b>LAB0012189v5</b>	SPECIAL INSTRUCTIONS/COMMENTS <b>n/a</b>	BINDING <b>n/a</b>	COLORS <b>Black, PMS 185C, PMS 266C</b>		
FLAT SIZE <b>20.16" x 5"</b> <b>512 mm x 127 mm</b>	FOLDED SIZE <b>4.03" x 5"</b> <b>102.36 mm x 127 mm</b>	RMC NUMBER <b>PM72434E</b>	PAGE COUNT <b>2</b>	LANGUAGES <b>EN</b>		SELF COVER <input checked="" type="checkbox"/>	PLUS COVER <input type="checkbox"/>	SEALING METHOD <b>n/a</b>	WAFER SEAL <input type="checkbox"/>
BLEED SIZE .5" (12.7 mm) <input type="checkbox"/> .125" (3.175 mm) <input type="checkbox"/>	NONE <input checked="" type="checkbox"/> BLEED ALL SIDES <input type="checkbox"/>	BLEED TOP <input type="checkbox"/>	BLEED RIGHT <input type="checkbox"/>	BLEED LEFT <input type="checkbox"/>	BLEED BOTTOM <input type="checkbox"/>	<b>DRAWING IS NOT TO SCALE:</b> DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK. This document or data herein or herewith is not to be reproduced, used or disclosed in whole or part without the permission of Ethicon, Inc.			
STOCK <b>40 lb. Finch Opaque</b>					<b>ETHICON</b>				